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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,126	11/29/2001	Judith Aronhime	1662/50308	3388

26646 7590 02/26/2003

KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/997,126

Applicant(s)

ARONHIME ET AL.

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-146 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-146 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-146 are pending in this application.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to compounds, classified in class 548, subclass 537+.
- II. Claims 8-26 drawn to compounds, classified in class 548, subclass 537+.
- III. Claim 7, drawn to process, classified in class 548, subclass 537+.
- IV. Claims 27-29, drawn to process, classified in class 548, subclass 537+.
- V. Claims 30-34, drawn to a process, classified in class 548, subclass 537+.
- VI. Claims 35 and 36, drawn to a process, classified in class 548, subclass 537+.
- VII. Claims 37 and 38, drawn to a process, classified in class 548, subclass 537+.
- VIII. Claims 39-41, drawn to a process, classified in class 548, subclass 537+.
- IX. Claims 42-49 and 70, drawn to a process, classified in class 548, subclass 537+.
- X. Claim 50-66, drawn to a compound, classified in class 548, subclass 537+.
- XI. Claims 67-69 and 71-74, drawn to a process, classified in class 548, subclass 537+.
- XII. Claims 75-77, drawn to a process, classified in class 548, subclass 537+.
- XIII. Claims 78-82, drawn to a process, classified in class 548, subclass 537+.

- XIV. Claims 83-98, drawn to compounds, classified in class 548, subclass 537+.
- XV. Claims 99-103, drawn to a process, classified in class 548, subclass 537+.
- XVI. Claims 104-108, drawn to a compound, classified in class 548, subclass 537+.
- XVII. Claims 109-110, drawn to a process, classified in class 548, subclass 537+.
- XVIII. Claim 111, drawn to a process, classified in class 548, subclass 537+.
- XIX. Claims 112-115, drawn to a compound, classified in class 548, subclass 537+.
- XX. Claim 116, drawn to a process, classified in class 548, subclass 537+.
- XXI. Claim 117, drawn to a process, classified in class 548, subclass 537+.
- XXII. Claim 118, drawn to process, classified in class 548, subclass 537+.
- XXIII. Claims 119-123, drawn to a process, classified in class 548, subclass 537.
- XXIV. Claims 124-126, drawn to a process, classified in class 548, subclass 537+.
- XXV. Claims 127-130, drawn to a process, classified in class 548, subclass 537+.
- XXVI. Claims 131-133, drawn to a process, classified in class 548, subclass 537+.
- XXVII. Claim 134, drawn to a process, classified in class 548, subclass 537+.

XXVIII. Claim 135-136, drawn to a process, classified in class 548, subclass 537+.

XXIX. Claims 137-141, drawn to a process, classified in class 548, subclass 537+.

XXX. Claims 142 and 143, drawn to a process, classified in class 548, subclass 537+.

XXXI. Claim 144, drawn to a composition, classified in class 548, subclass 537+.

XXXII. Claim 145, drawn to a method of use, classified in class 548, subclass 537+.

XXXIII. Claim 146, drawn to a pharmaceutical dosage form, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and I, IV and II, V and II, VIII and II, IX and II, XI and X, XV and XIV, XVII and XVI, XVIII and XVI, XX and XIX, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. For example, Inventions IV, V and VIII are all drawn to processes of preparing atorvastatin hemi-calcium Form VIII, Inventions VI and VII are both drawn to processes of preparing atorvastatin hemi-calcium, and

Inventions XI and XII are both drawn to processes of preparing atorvastatin hemi-calcium Form IX.

Inventions I, II, X, XIV, XVI, XIX, XIX, and XXXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product. Applicants submit that "statin drugs are currently the most therapeutically effective drugs available for reducing low density lipoprotein (LDL) particle concentration in the blood stream of patients at risk for cardiovascular disease" (see the specification, page 1, lines 24-27). Therefore, statin drugs (even those beyond the instant compounds) are useful as claimed in claim 145.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

  
\_\_\_\_\_  
Joseph K. McKane

Supervisory Examiner

Group 1600

Sonya Wright

February 21, 2003